# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Comparison of analgesic effect of paracetamol versus pethidine in labor

### Protocol summary

**Study aim**
Comparison of analgesic effect of paracetamol versus pethidine in labor

**Design**
In this interventional study, 100 pregnant women who are candidates for natural childbirth will be selected and divided into two groups using block randomization method (n=50 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen.

**Settings and conduct**
Upon starting the active phase of labor intervention group1 will receive intravenous Paracetamol 1g/6.7 ml (CaspianTamin Co.) and 1 ml intramuscular placebo injectionin and intervention group 2 will receive intramuscular Pethidine 50 mg/1 ml (CaspianTamin Co.) and 6.7 ml intravenous placebo injection.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Over 37 weeks pregnancy, first or second pregnancy, singleton. Exclusion criteria: Malpresentation of fetus، macrosomia.

**Intervention groups**
Intervention group 1: Intravenous Paracetamol 1g /6.7 ml (CaspianTamin Co.) and 1 ml intramuscular placebo injection. Intervention group 2: Intramuscular Pethidine 50 mg/1 ml (CaspianTamin Co.) and 6.7 ml intravenous placebo injection.

**Main outcome variables**
pain

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20150808023559N17**
Registration date: **2018-03-24, 1397/01/04**
Registration timing: **prospective**

Last update: **2018-03-24, 1397/01/04**
Update count: **0**

**Registration date**
2018-03-24, 1397/01/04

**Registrant information**

**Name**
Somaieh Matin

**Name of organization / entity**
Ardabil University of Medicine Sciences

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-04-19, 1397/01/30

**Expected recruitment end date**
2018-06-20, 1397/03/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of analgesic effect of paracetamol versus pethidine in labor

**Public title**
Labor pain relief with paracetamol and pethidine

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Over 37 weeks pregnancy First or second pregnancy Singleton

**Exclusion criteria:**
Malpresentation of fetus Macrosomia

**Age**
No age limit

**Gender**
Female

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **100**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients are assigned randomly by blocking in one of the two specified groups and after selecting the envelope for each patient, before starting the treatment regimen envelope will be opened and based on the protocol, one of two methods will be selected.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Participants and clinical caregivers are not aware of the type of medication

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Ardabil University of Medical Sciences

**Street address**
Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

**City**
Ardabil

**Province**
Ardabil

**Postal code**
5615783134

**Approval date**
2017-12-31, 1396/10/10

**Ethics committee reference number**
IR.ARUMS.REC.1396.202

## Health conditions studied

### 1

**Description of health condition studied**
Labor pain

**ICD-10 code**
O80, O84

**ICD-10 code description**
Delivery

## Primary outcomes

### 1

**Description**
Pain

**Timepoint**
Before analgesic administrations and two times (30 and 60 min) after intervention

**Method of measurement**
Visual analog scale

## Secondary outcomes

### 1

**Description**
Apgar

**Timepoint**
1 and 5 minutes after birth

**Method of measurement**
Apgar test

## Intervention groups

### 1

**Description**
Intervention group: Intravenous Paracetamol 1g /6.7 ml (CaspianTamin Co.) and 1 ml intramuscular placebo injection

**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: Intramuscular Pethidine 50 mg/1 ml (CaspianTamin Co.) and 6.7 ml intravenous placebo injection

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Alavi Hospital

**Full name of responsible person**
Farnaz Enamzade
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## Sponsors / Funding sources

**1**

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**Name of organization / entity**
Ardabil University of Medical Sciences
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Ardabil University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Ardabil University of Medical Sciences
**Full name of responsible person**
Farnaz Enamzade
**Position**
Gynecology Asisstant
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available